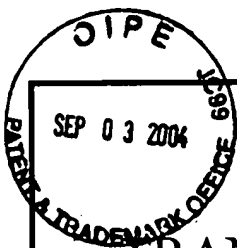


IPW



# TRANSMITTAL FORM

Application Serial Number	10/603,064
Filing Date	June 24, 2003
First Named Inventor	Gillies
Group Art Unit	1646
Examiner Name	Mertz, P.
Attorney Docket No.	LEX-010C1
Confirmation No.	8576
Patent No.	Not applicable
Issue Date	Not applicable

## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form (1 pg.) <input type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form  <input type="checkbox"/> Amendment <input type="checkbox"/> Supplemental Preliminary After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ]  <input type="checkbox"/> Petition for Extension of Time  <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of Supp. IDS Citations (A83-A99; B81; and C196-C218)  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Copy of the Notice to File Missing Parts  <input type="checkbox"/> Formal Drawing(s)  <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal  <input type="checkbox"/> Declaration and Power of Attorney  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Copy of the executed Declaration and Power of Attorney for Utility or Design Patent Application  <input type="checkbox"/> Small Entity Statement  <input type="checkbox"/> CD(s) for large table or computer program  <input type="checkbox"/> Amendment After Allowance  <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences  <input type="checkbox"/> Appeal Brief (in triplicate)  <input type="checkbox"/> Status Inquiry  <input checked="" type="checkbox"/> Return Receipt Postcard <input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8  <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8  <input type="checkbox"/> Additional Enclosure(s) (please identify below)
---	---	---

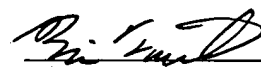
## CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator  
 Testa, Hurwitz & Thibault, LLP  
 High Street Tower  
 125 High Street  
 Boston, MA 02110  
 Tel. No.: (617) 248-7000  
 Fax No.: (617) 248-7100

## SIGNATURE BLOCK

Date: September 1, 2004  
 Reg. No. 48,645  
 Tel. No.: (617) 248-7697  
 Fax No.: (617) 248-7100

Respectfully submitted,

  
 Brian A. Fairchild, Ph.D.  
 Attorney for the Applicants  
 Testa, Hurwitz & Thibault, LLP  
 High Street Tower  
 125 High Street  
 Boston, MA 02110



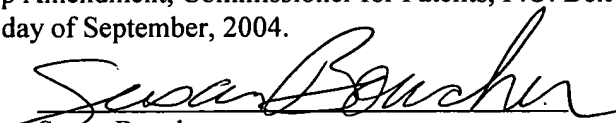
PATENT  
Attorney Docket No. LEX-010C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Gillies *et al.* CONF. NO.: 8576  
SERIAL NO.: 10/603,064 GROUP NO.: 1646  
FILING DATE: June 24, 2003 EXAMINER: P. Mertz  
TITLE: Multiple Cytokine Protein Complexes

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on this 1st day of September, 2004.

  
Susan Boucher

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Submitted herewith are:

1. Transmittal Form (1 pg.);
2. Supplemental Information Disclosure Statement (2 pgs.);
3. Form PTO-1449 (3 pgs.);
4. Cited references A83-A99, B81, and C196-C218; and
5. a return receipt postcard.



PATENT  
Attorney Docket No. LEX-010C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Gillies *et al.* CONF. NO.: 8576  
SERIAL NO.: 10/603,064 GROUP NO.: 1646  
FILING DATE: June 24, 2003 EXAMINER: P. Mertz  
TITLE: Multiple Cytokine Protein Complexes

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.


Applicants believe no fee is required at this time. If a fee is required, please charge Deposit Account 20-0531.

Respectfully submitted,

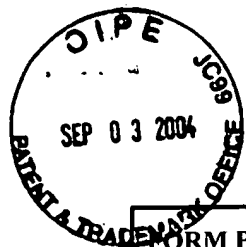
Date: September 1, 2004  
Reg. No. 48,645

Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7100

3112890\_1



\_\_\_\_\_  
Brian Fairchild, Ph.D.  
Attorney for Applicants  
Testa, Hurwitz, & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110



FORM PTO - 1449				ATTORNEY DOCKET NO.: LEX-010C1					
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT				APPLICANT(S): Gillies <i>et al.</i>					
				SERIAL NO.: 10/603,064					
				FILING DATE: June 24, 2003      GROUP: 1646					
U.S. PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	A83	5,601,819	2/11/97	Wong et al.					
	A84	5,891,680	4/6/99	Lieschke et al.					
	A85	5,994,104	11/30/99	Anderson et al.					
	A86	6,429,199	8/6/02	Krieg et al.					
	A87	6,500,641	12/31/02	Chen et al.					
	A88	6,551,592	4/22/03	Lindhofer et al.					
	A89	6,646,113	11/11/03	Dreyfuss et al.					
	A90	2002/0037558	3/28/02	Lo et al.					
	A91	2002/0146388	10/10/02	Gillies					
	A92	2003/0139365	7/24/03	Lo et al.					
	A93	2003/0139575	7/24/03	Gillies					
	A94	2004/0013640	1/22/04	Zardi et al.					
	A95	2004/0033210	2/19/04	Gillies					
	A96	2004/0043457	3/4/04	Schumacher et al.					
	A97	2004/0053366	3/18/04	Lo et al.					
	A98	2004/0072299	4/15/04	Gillies et al.					
	A99	2004/0082039	4/29/04	Gillies et al.					
FOREIGN PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B81	WO 93/20185	10/14/93	PCT					
EXAMINER					DATE CONSIDERED				

FORM PTO - 1449		ATTORNEY DOCKET NO.: LEX-010C1
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		APPLICANT(S): Gillies <i>et al.</i>
		SERIAL NO.: 10/603,064
		FILING DATE: June 24, 2003      GROUP: 1646
OTHER ART, JOURNAL ARTICLES, ETC.		
	C196	Chapman et al., (1994), "Mapping Effector Functions of a Monoclonal Antibody to GD3 by Characterization of a Mouse-Human Chimeric Antibody," <u>Cancer Immuno. Immunother.</u> , 39:198-204.
	C197	Conner et al., (2004), "Ex vivo Evaluation of Anti-EpCAM Immunocytokine huKS-IL2 in Ovarian Cancer," <u>J. Immunotherapy</u> , 27:211-219.
	C198	de la Salle et al., (1996), "FcγR on Human Dendritic Cells," in <u>Human IgG Receptors</u> , pp. 39-55, van de Winkel et al. (eds.), R.G. Landes Co.
	C199	Dorai et al., (1991), "Aglycosylated Chimeric Mouse/Human IgG1 Antibody Retains Some Effector Function," <u>Hybridoma</u> , 10(2):211-217.
	C200	Dorai et al., (1992), "Role of Inter-Heavy and Light Chain Disulfide Bonds in the Effector Functions of Human IgG1," <u>Molecular Immunology</u> , 29(12):1487-1491.
	C201	Elliott et al., (1996), "Fine-Structure Epitope Mapping of Antierythropoietin Monoclonal Antibodies Reveals a Model of Recombinant Human Erythropoietin Structure," <u>Blood</u> , 87(7):2702-2713.
	C202	Gillies et al., (1991), "Targeting Human Cytotoxic T Lymphocytes to Kill Heterologous Epidermal Growth Factor Receptor-Bearing Tumor Cells: Tumor-Infiltrating Lymphocyte/Hormone Receptor/Recombinant Antibody," <u>J. Immunology</u> , 146(3):1067-1071.
	C203	Handgretinger et al., (1995), "A Phase I Study of Human/Mouse Chimeric Anti-ganglioside GD2 Antibody ch14.18 in Patients with Neuroblastoma," <u>European J. Cancer</u> , 31A(2):261-267.
	C204	Hurn et al., (1980), "Production of Reagent Antibodies," <u>Methods in Enzymology</u> , 70: 104-142.
	C205	Isenman et al., (1975), "The Structure and Function of Immunoglobulin Domains: II. The Importance of Interchain Disulfide Bonds and the Possible Role of Molecular Flexibility in the Interaction between Immunoglobulin G and Complement," <u>J. Immunology</u> , 114(6):1726-1729.
	C206	Ko et al., (2004), "Safety, Pharmacokinetics, and Biological Pharmacodynamics of the Immunocytokine EMD 273066 (huKS-IL2)," <u>J. Immunotherapy</u> , 27:232-239.
	C207	Lo et al., (1992), "Expression and Secretion of an Assembled Tetrameric CH2-deleted Antibody in <i>E. Coli</i> ," <u>Hum. Antibod. Hybridomas</u> , 3:123-128.
	C208	Maecker et al., (1997), "DNA Vaccination with Cytokine Fusion Constructs Biases the Immune Response to Ovalbumin," <u>Vaccine</u> , 15(15):1687-1696.
	C209	Mueller et al., (1990), "Enhancement of Antibody-Dependent Cytotoxicity With A Chimeric Anti-GD2 Antibody," <u>J. Immunology</u> , 144(4):1382-1386.
EXAMINER		DATE CONSIDERED

<b>FORM PTO - 1449</b>		<b>ATTORNEY DOCKET NO.:</b> LEX-010C1
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b>		<b>APPLICANT(S):</b> Gillies <i>et al.</i>
		<b>SERIAL NO.:</b> 10/603,064
		<b>FILING DATE:</b> June 24, 2003 <b>GROUP:</b> 1646
<b>OTHER ART, JOURNAL ARTICLES, ETC.</b>		
	C210	Mueller et al., (1990), "Serum Half-Life and Tumor Localization of a Chimeric Antibody Deleted of the CH2 Domain and Directed Against the Disialoganglioside GD2," <u>Proc. Natl. Acad. Sci. USA.</u> , 87:5702-5705.
	C211	Naramura et al., (1993), "Therapeutic Potential of Chimeric and Murine Anti-(Epidermal Growth Factor Receptor) Antibodies in a Metastasis Model for Human Melanoma," <u>Cancer Immuno. Immunother.</u> , 37:343-349.
	C212	Pertl et al., (2003), "Immunotherapy with a Posttranscriptionally Modified DNA Vaccine Induces Complete Protection Against Metastatic Neuroblastoma," <u>Blood</u> , 101(2):649-654.
	C213	Reisfeld et al., (1994), "Potential of Genetically Engineered Anti-Ganglioside GD2 Antibodies for Cancer Immunotherapy," <u>Prog. Brain Res.</u> , 101:201-212
	C214	Saleh et al., (1992), "Phase I Trial of the Chimeric Anti-GD2 Monoclonal Antibody ch14.18 in Patients With Malignant Melanoma," <u>Hum. Antiob. Hybridomas</u> , 3:19-24.
	C215	Sallusto et al., (1994), "Efficient Presentation of Soluble Antigen by Cultured Human Dendritic Cells Is Maintained by Granulocyte/Macrophage Colony-stimulating Factor Plus Interleukin 4 and Downregulated by Tumor Necrosis Factor $\alpha$ ," <u>J. Exp. Med.</u> , 179:1109-1118.
	C216	Schlom (1991), "Monoclonal Antibodies: They're More and Less Than You Think," in <u>Molecular Foundations of Oncology</u> , pp. 95-133.
	C217	Weber et al., (2001), "Phase I Trial of huKS-IL2 Immunocytokine in Patients with Prostate Carcinoma: Clinical, PK, and Biological PD Results (Abstract)," <u>American Society of Clinical Oncology Program/Proceedings</u> , 20(Part 1):259a.
	C218	Wen et al., (1994), "Erythropoietin Structure-Function Relationships: Identification of Functionally Important Domains," <u>J. Biological Chemistry</u> , 269(36):22839-22846.
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>